
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 7, 2020

COHERUS BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36721
(Commission
File Number)

27-3615821
(IRS Employer
Identification Number)

333 Twin Dolphin Drive, Suite 600
Redwood City, CA 94065
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (650) 649-3530

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	CHRS	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Conditions

On May 7, 2020, the Company issued a press release regarding its financial results for its first quarter ended March 31, 2020. The full text of the press release is furnished as Exhibit 99.1 to this Form 8-K.

This information in this Item 2.02 of this Form 8-K and the Exhibit 99.1 attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section, or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. Description

99.1 [Press release dated May 7, 2020.](#)

104 Cover page Interactive Data file (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 7, 2020

COHERUS BIOSCIENCES, INC.

By: /s/ Jean-Frédéric Viret

Name: Jean-Frédéric Viret

Title: Chief Financial Officer



Coherus BioSciences Reports First Quarter 2020 Financial Results

- First Quarter UDENYCA® Net Sales of \$116.2 Million –
- Net Income of \$35.6 Million –
- Non-GAAP Net Income of \$49.8 Million –

REDWOOD CITY, Calif., May 7, 2020 – Coherus BioSciences, Inc. (“Coherus” or the “Company”, Nasdaq: CHRS), today reviewed corporate events and reported financial results for the quarter ended March 31, 2020.

First Quarter 2020 and Recent Corporate Highlights

- **Strong financial position and performance to support pipeline development and long-term growth:**
 - o Coherus had cash and cash equivalents of \$193.3 million as of March 31, 2020.
 - o Completed a convertible notes financing for an aggregate principal amount of \$230 million at a 1.500% coupon in April 2020. The net proceeds from this financing will be used for opportunistic pipeline acquisitions or licenses, working capital, and for other general corporate purposes, which may include debt repayment in the future.
 - o Cash flow from operating activities was \$13.5 million for the first quarter of 2020.
 - o Net product revenue for the first quarter of 2020 was \$116.2 million, and net income was \$35.6 million, or \$0.48 per share on a diluted basis.
 - o Non-GAAP income during the first quarter of 2020 was \$49.8 million, or \$0.67 on a diluted basis.
 - o Coherus has remained cash flow positive since the second quarter of 2019.
- **Coherus completed a key licensing transaction in oncology to enhance its midterm product pipeline in the United States:**
 - o Entered into a license agreement with Innovent Biologics, (Suzhou) Co., Ltd., (“Innovent”), a leading biopharmaceutical company headquartered in China, to commercialize Innovent’s biosimilar candidate to Avastin® (bevacizumab) in the United States and Canada.

First Quarter 2020 Financial Results

Net product revenue for first quarter of 2020 was \$116.2 million. Cost of goods sold for the same quarter was \$6.9 million, resulting in a gross profit margin of 94%, a 213% increase compared to the net product revenue of \$37.1 million for the same period in 2019. Net product revenue increased year-over-year markedly as a result of market penetration.

Research and development (R&D) expenses for the first quarter 2020 were \$33.1 million, as compared to \$18.8 million for the same period in 2019. The increase in R&D expenses was largely due to an upfront payment obligation of \$5.0 million pursuant to the Innovent license agreement and increased expenses related to

preparations for the filing of the 351(k) BLA for CHS-1420 (Humira® (adalimumab) biosimilar) and the development of other biosimilar product candidates.

Selling, general and administrative (SG&A) expenses for the first quarter of 2020 were \$35.4 million, as compared to \$32.7 million for the same period in 2019. The increases in SG&A expenses were mainly attributable to an increase in salesforce personnel, related commercial functions and marketing programs to support the continued growth in UDENYCA® sales. The increases were partially offset by a decrease in legal costs attributable to the legal settlement that the Company entered into with Amgen in May 2019.

Cash, cash equivalents were \$193.3 million as of March 31, 2020, as compared to \$177.7 million as of December 31, 2019.

Net income (loss) for the first quarter of 2020 was \$35.6 million, or \$0.48 per share on a diluted basis, compared to a net loss of (\$20.0) million, or (\$0.29) per share on a basic and diluted basis for the same period in 2019.

Non-GAAP net income (loss) for the first quarter of 2020 was \$49.8 million, or \$0.67 per share on a diluted basis, compared to a non-GAAP net loss of (\$10.5) million, or (\$0.15) per share on a basic and diluted basis for the same period in 2019. See “Non-GAAP Financial Measures” below for a discussion on how we calculate non-GAAP net income (loss) and a reconciliation to the most directly comparable GAAP measure.

Guidance for the Next Nine Months from March 31, 2020

Coherus will continue delivering on the promise of biosimilars and laying the foundation for long-term growth across its three therapeutic areas:

Oncology

- UDENYCA® (pegfilgrastim-cbqv)
 - Maintain market position as the leading pegfilgrastim biosimilar of choice leveraging the validated branded-biosimilar strategy of offering a robust value proposition across all key customer segments.
 - Increase penetration against all Neulasta® dosage forms, while maintaining average selling price (“ASP”) discipline.
- Advance the Company’s Avastin® (bevacizumab) oncology biosimilar candidate in-licensed from Innovent by initiating a planned three-way pharmacokinetic (“PK”) study using innovator Avastin® drug articles from the United States and China compared to Innovent’s biosimilar to bevacizumab, and additional analytical similarity exercises. The Company expects to submit a 351(k) BLA with the FDA in 2021, depending on the outcome of these exercises and the timing of required interactions with the FDA.
- Diligence the option to commercialize Innovent’s Rituxan® (rituximab) oncology biosimilar in the United States.

Ophthalmology

- Facilitate Bioeq’s resubmission of a 351(k) BLA with the U.S. FDA for the biosimilar candidate to Lucentis® (ranibizumab) in the second half of 2020, with expected product launch in the United States to address a \$6 billion anti-VEGF ophthalmology market, if approved, enabling the Company to potentially play a key role in market formation.
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- Advance the Company’s internally developed CHS-2020 Eylea® (aflibercept) ophthalmology biosimilar currently in preclinical development to an expected Phase 3 clinical trial initiation in 2021, with launch projected in 2025, if approved.

Immunology

- Advance certain manufacturing, regulatory and development activities for the Company’s internally developed CHS-1420 immunology biosimilar to Humira® (adalimumab) with an anticipated filing of a 351(k) BLA in the second half of 2020. The Company expects this timing will enable a projected competitive market entry in the United States on or after July 1, 2023, if approved.

CHS-131

- Advance previously announced strategic alternatives for the Company’s program in CHS-131, a small molecule for nonalcoholic steatohepatitis (“NASH”) and multiple sclerosis.

Financial Guidance

- Anticipate that R&D and SG&A expenses combined together will range between \$285 million and \$310 million for the full fiscal year 2020, excluding upfront and milestone payments from entering into potential new collaborations.

Conference Call Information

When: Thursday, May 7, 2020 starting at 4:30 p.m. ET

Dial-in: (844) 452-6826 (Toll Free) or (765) 507-2587 (International)

Conference ID: 6167564

Webcast: <https://investors.coherus.com/>

Please join the conference call at least 10 minutes early to register. The webcast will be archived on the Coherus website.

First quarter 2020 financial results, are posted on the Coherus website at <https://investors.coherus.com/>.

About Coherus BioSciences, Inc.

Coherus is a leading biosimilar company that develops and commercializes its own high-quality therapeutics as well as those of others seeking capable access to the United States market. Biosimilars are intended for use in place of existing, branded biologics to treat a range of chronic and often life-threatening diseases, with the potential to reduce costs and expand patient access. Composed of a team of proven industry veterans with world-class expertise in process science, analytical characterization, protein production, sales and marketing and clinical-regulatory development, Coherus is positioned as a leader in the global biosimilar marketplace. Coherus commercializes UDENYCA® (pegfilgrastim-cbqv) in the United States and has received regulatory approval for UDENYCA® in the European Union. Coherus is advancing late-stage clinical products CHS-1420, a Humira® (adalimumab) biosimilar, Bioeq’s Lucentis® (ranibizumab) biosimilar and Innovent’s Avastin® (bevacizumab) biosimilar towards commercialization, and early-stage clinical products, CHS-2020, an Eylea® (aflibercept) biosimilar, and CHS-131, a small molecule for nonalcoholic steatohepatitis (NASH) and multiple sclerosis. For additional information, please visit www.coherus.com.

Forward-Looking Statements

Except for the historical information contained herein, the matters set forth in this press release are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, Coherus' ability to continue delivering on the promise of biosimilars and laying the foundation for long-term growth across its three therapeutic areas; Coherus' ability to continue to maintain market position as the leading pegfilgrastim biosimilar of choice leveraging the validated branded-biosimilar strategy of offering a robust value proposition across all key customer segments; Coherus' ability to continue to increase penetration in market share from both Neulasta® Onpro® and Neulasta® prefilled syringe; Coherus' ability to maintain ASP discipline for UDENYCA®; Coherus' ability to advance its Avastin® (bevacizumab) oncology biosimilar candidate in-licensed from Innovent by completing a three-way PK study, as well as completing additional analytical similarity exercises; Coherus' ability to submit a 351(k) BLA with the FDA in 2021, for the Innovent biosimilar candidate to Avastin®; Coherus' ability to launch Innovent's biosimilar candidate to Avastin® in the United States; Coherus' ability to facilitate Bioeq's resubmission of a 351(k) BLA with the U.S. FDA for the biosimilar candidate to Lucentis® (ranibizumab) in the second half of 2020 and Coherus' ability to launch the product, if approved; Coherus' ability to advance CHS-2020 Eylea® (aflibercept) ophthalmology biosimilar currently in preclinical development by initiating an expected Phase 3 clinical trial in 2021, with launch projected in 2025, if approved; Coherus' ability to complete certain manufacturing, regulatory and development activities for CHS-1420 with an anticipated filing of a 351(k) BLA in the second half of 2020; Coherus' ability to have a competitive market entry in the United States on or after July 1, 2023 for CHS-1420; Coherus' plans to pursue strategic alternatives for its program in CHS-131; and Coherus' ability to meet its R&D and SG&A expenses guidance for the full fiscal year 2020. Such forward-looking statements involve substantial risks and uncertainties that could cause Coherus' actual results, performance or achievements to differ significantly from any future results, performance or achievements expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the risks and uncertainties inherent in the clinical drug development process; the risks and uncertainties of the regulatory approval process, including the timing of Coherus' regulatory filings; the risk that Coherus is unable to complete commercial transactions and other matters that could affect the availability or commercial potential of Coherus' biosimilar drug candidates; and the risks and uncertainties of possible patent litigation. All forward-looking statements contained in this press release speak only as of the date on which they were made. Coherus undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Coherus' business in general, see Coherus' Quarterly Report on Form 10-Q for the three months ended March 31, 2020, to be filed with the Securities and Exchange Commission on May 7, 2020 and its future periodic reports to be filed with the Securities and Exchange Commission. Our results for the quarter ended March 31, 2020 are not necessarily indicative of our operating results for any future periods.

UDENYCA® is a trademark of Coherus BioSciences, Inc.

Neulasta® and Onpro® are registered trademarks of Amgen Inc.

Avastin®, Rituxan® and Lucentis® are registered trademarks of Genentech, Inc.

Humira® is a registered trademark of AbbVie Inc.

Eylea® is a registered trademark of Regeneron Pharmaceuticals, Inc.

Coherus BioSciences, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)

	Three Months Ended	
	March 31,	
	<u>2020</u>	<u>2019</u>
	<i>(unaudited)</i>	
Revenue:		
Net product revenue	\$ 116,180	\$ 37,098
Operating expenses:		
Cost of goods sold	6,855	2,225
Research and development	33,107	18,789
Selling, general and administrative	35,350	32,683
Total operating expenses	<u>75,312</u>	<u>53,697</u>
Income (loss) from operations	40,868	(16,599)
Interest expense	(4,431)	(4,216)
Other income, net	68	811
Net income (loss) before income taxes	36,505	(20,004)
Income tax provision	933	-
Net income (loss)	<u>\$ 35,572</u>	<u>\$ (20,004)</u>
Net income (loss) per share:		
Basic	\$ 0.50	\$ (0.29)
Diluted	\$ 0.48	\$ (0.29)
Weighted-average number of shares used in computing net income (loss) per share:		
Basic	70,662,185	69,140,697
Diluted	74,416,554	69,140,697

Coherus BioSciences, Inc.
Condensed Consolidated Balance Sheets
(in thousands)

	March 31,	December 31,
	2020	2019
	<i>(unaudited)</i>	
Assets		
Cash and cash equivalents	\$ 193,252	\$ 177,668
Trade receivables, net	167,450	141,992
Inventory	65,068	55,071
Other assets	40,769	34,196
Total assets	<u>\$ 466,539</u>	<u>\$ 408,927</u>
Liabilities and Stockholders' Equity		
Accrued rebate, fees and reserve	\$ 66,157	\$ 51,120
Convertible notes	78,866	78,542
Convertible notes - related parties	26,289	26,181
Term loan	73,858	73,663
Other liabilities	64,094	74,207
Total stockholders' equity	157,275	105,214
Total liabilities and stockholders' equity	<u>\$ 466,539</u>	<u>\$ 408,927</u>

Coherus BioSciences, Inc.
Condensed Consolidated Cash Flow
(in thousands)

	Three Months Ended	
	March 31,	
	2020	2019
	<i>(unaudited)</i>	
Cash, cash equivalents and restricted cash at beginning of the period	\$ 177,908	\$ 73,191
Net cash provided by (used in) operating activities	\$ 13,477	\$ (56,983)
Purchases of investments in marketable securities	–	(14,864)
Purchases of property and equipment and cash used in other investing activities	(1,616)	(335)
Net cash used in investing activities	\$ (1,616)	\$ (15,199)
Proceeds from term loan, net of issuance costs	–	72,876
Proceeds from common stock offering, net of underwriters discounts, commissions and offering costs	–	8,153
Proceeds from issuance of common stock upon exercise of stock options	4,803	448
Cash used in other financing activities	(880)	–
Net cash provided by financing activities	\$ 3,923	\$ 81,477
Effect of exchange rate changes on cash	–	(136)
Net increase in cash, cash equivalents and restricted cash	\$ 15,784	\$ 9,159
Cash, cash equivalents and restricted cash at end of the period	\$ 193,692	\$ 82,350
Reconciliation of cash, cash equivalents, and restricted cash		
Cash and cash equivalents	193,252	81,515
Restricted cash balance	440	835
Cash, cash equivalents and restricted cash	\$ 193,692	\$ 82,350

Non-GAAP Financial Measures

To supplement the financial results presented in accordance with GAAP, Coherus has also included in this press release non-GAAP net income (loss), and the related per share measures, which exclude from net income (loss), and the related per share measures, stock-based compensation expense, upfront and milestone payments under the license agreements and the related income tax effect of those non-GAAP adjustments. These non-GAAP financial measures are not prepared in accordance with GAAP, do not serve as an alternative to GAAP and may be calculated differently than similar non-GAAP financial information disclosed by other companies. Coherus encourages investors to carefully consider its results under GAAP, as well as its supplemental non-GAAP financial information and the reconciliation between these presentations set forth below, to more fully understand Coherus' business.

Coherus believes that the presentation of these non-GAAP financial measures provides useful supplementary information to, and facilitates additional analysis by, investors. In particular, Coherus believes that these non-GAAP financial measures, when considered together with its financial information prepared in accordance with GAAP, can enhance investors' and analysts' ability to meaningfully compare Coherus' results from period to period, and to identify operating trends in Coherus' business. Coherus also regularly uses these non-GAAP financial measures internally to understand, manage and evaluate its business and to make operating decisions.

Coherus BioSciences, Inc. **Reconciliation of GAAP Net Income (Loss) to Non-GAAP Net Income (Loss)** *(in thousands, except share and per share data)*

	Three Months Ended	
	March 31,	
	2020	2019
	<i>(unaudited)</i>	
GAAP net income (loss)	\$ 35,572	\$ (20,004)
Adjustments:		
Stock based compensation expense	9,555	9,494
Upfront payment under the license agreement with Innovent	5,000	–
Income tax effect of the above adjustments	(362)	–
Non-GAAP net income (loss)	\$ 49,765	\$ (10,510)
GAAP net income (loss) per share, basic	\$ 0.50	\$ (0.29)
GAAP net income (loss) per share, diluted	\$ 0.48	\$ (0.29)
Non-GAAP net income (loss) per share, basic	\$ 0.70	\$ (0.15)
Non-GAAP net income (loss) per share, diluted	\$ 0.67	\$ (0.15)
Shares used in computing basic net income (loss) per share	70,662,185	69,140,697
Shares used in computing diluted net income (loss) per share	74,416,554	69,140,697

Contact

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